A STUDY TO ASSESS THE EFFECT OF ORAL ADMINISTRATION OF EXPRESSED BREAST MILK JUST BEFORE IV CANNULATION IN REDUCING CANNULATION PAIN AMONG THE NEONATES IN NICU IN THE SELECTED HOSPITAL AT KANYAKUMARI DISTRICT

DISSERTATION SUBMITTED TO

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY CHENNAI

IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE AWARD OF DEGREE OF MASTER OF SCIENCE IN NURSING

OCTOBER- 2014

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CERTIFICATE

This is to certify that the dissertation entitled "A Study To Assess The Effect of Oral Administration of Expressed Breast Milk Just Before IV Cannulation in Reducing Cannulation Pain Among The Neonates In NICU in The Selected Hospital at Kanyakumari District" is a bonafide work done by Mrs. Janeefa Shiny.M, IInd Year M.Sc Nursing, Global College of Nursing, Nattalam in partial fulfilment of the University rules and regulations for the award of M.Sc. (N) degree under my guidance and supervision during the academic year October 2012-2014.

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ABSTRACT

The present study is aimed to assess the effect of oral administration of EBM just before starting IV cannula in reducing cannulation pain among the neonates in NICU in the selected hospital .

The objectives of the study are,

1. To assess the level of pain during IV cannulation after oral administration of EBM in the group A and without EBM in group B.
2. To assess the effect of EBM in reducing cannulation pain by comparing the pain level between group A and group B.
3. To determine the association between the level of pain in group B during IV cannulation and their demographic variables such as age, sex, weight of the baby,type of delivery, previous experience of IV cannulation .

The investigator adopted Callista Roy's adaptation theory (1999) as the conceptual framework for the study. Quasi experimental post test only design with control group was used and the formal consent was obtained from PPK hospital and the investigator selected 60 samples using purposive sampling technique and who are fulfilling the inclusive criteria were selected as a samples both in experimental and control group. Measurement

of pain experienced by the neonate was assessed with the help of Neonatal Infant Pain Scale(NIPS).

Descriptive and inferential statistics were used to analyze the analyze the data. Analysis of demographic variables was done in terms of frequency and percentage distribution. Comparison of post test level of pain between the experimental and the control groups was analysed by‘t’ test .Which is an inferential statistical analysis. Association of post test level of pain in the control group with demographic variables was analysed by using chi-square test. The findings concluded that in the experimental group majority 16(53.33%) had mild pain and in control group majority 16(53.33%)had severe pain.

In the experimental group, the post test level of mean pain score was 2.3 with standard deviation 0.822 and in the control group the post test mean score was 4.43 with standard deviation 1.054. The mean difference score was ± 2.13. The calculated ‘t’ value of 8.247 was statistically significant at $P<0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

Hence the EBM was responsive in reducing the IV cannulation pain among neonates.

CHAPTER-I

INTRODUCTION

"*The child shall in all circumstances be among the first to receive protection and relief*."

-UN's Right of children.

Pain is a complex phenomenon for children, involving psychological, biological and sociological factors. The pains are often linked in the minds of children despite the advances in pediatric pain management during each procedure, the children continue to have moderate to severe pain that is not well controlled. This study evaluates available evidence about the effectiveness of administering expressed breast milk before starting IV cannulation in neonates in making the neonate calm.

Reports from children, parents and nurses consistently indicate that many children do indeed fear the shot. "This finding is also supported by research indicating that a majority of the adult population also suffer from fear involving needles".

The international association for the study of pain has defined pain as "An unpleasant sensory and emotional experience connected with actual or potential tissue damage or described in terms of such damage. "The myth regarding neonatal pain suggests that because of neurological immaturity,

neonates do not experience pain. studies have shown that pain pathways as well as cortical and sub-cortical centers, necessary for pain perception are well developed late in gestation and physiological and behavioral administration of responses to pain are well documented in neonates.

The response of children to an injection depend in part on their developmental ages, cognitive processes and their previous experiences with shots". A child's anxiety and fear of a procedure and actual pain experience during a procedure. Often are manifested by the child's behavior such as crying, flailing and refusal to cooperate. The child's distress is upsetting not only for the child but also for the adults involving both parents and professionals and it often makes more difficult to complete the needed procedure. A neonate results in a diffuse way by crying and making generalized body movements.

The complimentary and the non-pharmacological therapies tested on children include showing play materials, giving support, positioning, comforting, reassurance, touch (hand holding) most complimentary therapies successfully reduced discomfort among the neonates (Lassetter J .H).

Health care professionals should anticipate predictable painful experiences and monitor the condition of patient accordingly to treat pain adequately, ongoing assessment of the presence and severity of pain and the child's response to treatment is essential. Reliable, valid and clinically sensitive assessment tools are available for neonates through adolescents .pain

can be assessed using self-support, behavioral administration of observation, or physiological measures, depending on the age of the child and his or her communication capabilities. Specific measures vary in their validity and usefulness accurate acute pain assessment requires consideration of the plasticity and complexity of children's pain perception, the influence of psychological and developmental factors and the appreciation of the potential severity and specific types of pain experienced.

The parents of child has traditionally served as the chief support. Pain is a subjective experience and neonates respond to pain with behavioral administration of reactions that depend upon the cognitive processes .pain due to starting intravenous cannula to reduce that EBM is administered.

The neonate's degree of pain perception continues to be questioned. The young infant respond with total body movement associated with brief, loud crying that ceases with distraction by the end of 1st month of life. Pain in the children must be individualized age, sex, birth order, cultural background, parents, care giver's response and the newborn baby unable to localize and describe the severity of pain. The nurse must be aware of the Childs response to pain through assessment of behavioral administration of response and differentiation of crying.

While starting IV cannula there is concern that respiratory depression may occur in neonates. However although respiration may show, respiratory depression is not significant frequently. Children identify a pain as coming in

a shot or needle and refuse cannula. Having a supportive administering EBM can make a major difference to both the experience and outcome of stating IV cannula.

Treating procedural pain has become a crucial part of neonatal care. In healthy infants, the most common painful procedures are heel lance and venipuncture. Pharmacological treatments are rarely used during these procedures because of concerns about their effectiveness and potential adverse effects therefore, non pharmacological intervention are valuable alternatives .several therapeutic and preventive strategies ,including systemic and local pharmacological and non pharmacological interventions are reported to be effective in relieving pain in infants. A judicious application of these interventions, backed by awareness and sensitivity to pain perception, on the part of the caregivers is likely to yield the best results.

NEED FOR THE STUDY

If we see the hospital setting the invasive procedures such as IV insertion, IV medication and IV fluids administration blood sampling etc, are carried out more commonly and cause pain during the insertion time. The neonates can express their pain experience only through facial expression like crying, tightening of facial muscles etc. IV therapy is very common among infants during hospitalization. In India the incidence shows that 3,870 of infants between 1 to 6 months. Who is undergoing iv insertion (0.32 second)

2,540 infants getting iv medication (0.42 second)and 2,270 infants getting intravenous fluids (0.47 second)during hospitalization.

The Tamil Nadu incidence shows that 478 infants between1 to 6 months undergoing iv insertion (0.34 second),732 infants is getting iv medication (0.35 seconds), 664 infants is getting iv fluids (0.4 seconds)during hospitalization.

Ricardo carbajal(2003)conducted a study to investigate whether breast feeding is effective for pain relief during venipuncture in term neonate and compare any effect with that of oral administration of glucose combined with a pacifier .The study concluded that breast feeding effectively reduces response to pain during minor invasive procedure in term neonates.

Osinaike(2007)conducted a study to determine the analgesics effects of breast feeding during venepuncture and previous venipuncture and site venipuncture do not seem to affect pain scores. Breast feeding should be the first choice analgesics during painful procedures in neonates.

Raylene M. Phillips (2005) conducted a study to compare analgesics effects of breast feeding vs pacifier use in newborn infants undergoing blood collection via heel stick. Second to compare analgesic effect of pacifier use with maternal holding vs non maternal holding. The study concluded the breast feeding is more analgesic than non maternal holding with pacifier use suggesting that maternal holding itself has an analgesics effect .Breast feeding

and maternal holding should be considered as pain control measures for the neonate during heel stick procedures.

P.J .Mathew (2003)long term effect on behavior and development intervention are reported are reported to be effective in relieving pain in infants ,a case study reflecting this aspect of pain response another aspect that must be looked into before administering of these breast feeding.

S.Mathai (2006)at 30 seconds after the stimulus the pain score were lowest in the sucrose despite an increase awareness regarding pain in neonates and its deter mental effect DAN score was assessed before giving the stimulus and again at 30 seconds to receive one of the following interventions EBM.

During the invasive procedure the neonates were separated from parents for various investigations and further it increases the pain. In some private hospital babies are handled by untrained and unskilled health professionals who also increase the pain for the baby.

Relief of pain is a basic need and right of all children .Reducing discomfort routine procedure, such as venepuncture or an IV cannula insertion, IV medication administration, etc can contribute the perceived satisfaction. A countless number of neonates experience painful procedure such as venipuncture, intravenous medication, IV fluids are routine fact of primary care or diagnostic procedure for infants. Skin to skin contact has been shown to decrease the pain of minor procedure breast milk and breast feeding has also shown to be analgesics.

In foreign setups many researches are conducted and they proved that breast feeding effectively reduces response to pain during minor invasive procedure in neonates. In our setup lack of studies related to this topic and also there is a lack of awareness among health professionals regarding effects of EBM in pain reduction.

Based on the investigators experience, observation and interest intravenous cannula insertion is a very common procedures, immediately after hospitalization of the child. But during insertion of intravenous cannula the parents and children undergo stress because of pain. To overcome this stress the investigator was interested to do study on the effects of EBM in pain reduction during iv therapy procedures.

Statement of the problem:

"A STUDY TO ASSESS THE EFFECT OF ORAL ADMINISTRATION OF EBM JUST BEFORE IV CANNULATION IN REDUCING CANNULATION PAIN AMONG THE NEONATES IN NICU IN THE PPK HOSPITAL AT KANYAKUMARI DISTRICT".

Objectives:

1. To assess the level of pain during IV cannulation after oral administration of EBM to group A and without EBM to group B.
2. To assess the effect of EBM in reducing cannulation pain by comparing the pain level between group A and group B.

3. To determine the association between the level of pain in group B during IV cannula and their selected demographic variables such as age, sex, weight of the baby, type of delivery, previous experience of IV cannulation.

Hypotheses:

- H_1 There is a significant difference of pain level during IV cannulation between groups A and B.
- H_2 There is a significant association between pain in group B and their demographic variables such as age, sex, weight of the baby, type of the delivery, previous experience of IV cannulation.

Assumption:

1. All the neonates may experience pain during IV cannulation.
2. Oral administration of EBM just before IV cannulation may reduce pain for the neonates.

Delimitations of the study:

The study was delimited to,

1. Only neonates at the age 0-7 days.

2. Only neonates requiring IV cannulation for fluid infusion.

3. Only 60 samples.

4. Only one NICU.

5. Only 4 weeks for data collection.

OPERATIONAL DEFINITION:

Effect:

In this study it refers to, a desired outcome of reducing IV cannulation pain after oral administration of EBM in the selected neonates as measured by Neonatal Infant pain scale (NIPS).

Oral administration of Expressed Breast Milk:

In this study it refers to, giving 5ml of breast milk released manually from the mother's breast by fixing a pump and given to the neonate oral administration ofly by paladai.

IV cannulation:

In this study it refers to, Introducing a sterile polyethylone tube along with a stillet into the vein of the neonates, for the purpose of infusing fluid

Reducing cannulation pain:

In this study it refers to, bringing down the pain level in neonates during the insertion of sterile polyethylone tube into the vein due to oral administration of EBM, as measured by Neonatal Infant Pain Scale(NIPS)

Neonates:

In this study it refers to, the babies between the age group of birth to 7 days, who required IV cannulation for fluid infusion.

Neonatal intensive care unit:

In this study it refers to ,The cubicle in the pediatric unit ,which accomodates only very ill newborns within 28 days of birth who require specialized /emergency care.

Conceptual Framework

Introduction:

The conceptual framework provides a certain frame reference for clinical, education and research. It gives direction to research for relevant question, phenomenon and points out solution to practical problem.

Conceptual framework refers to interrelated concepts or abstractions that are assembled together in some rational scheme by virtue of their relevance of a common theme (Polit and Hunger-1999).

Theoretical model for this study was derived from Callista Roy's adaptation model (1999). According to Roy's adaptation model the goal of nursing is to facilitate adaptation between the person and the environment through the management of stimuli.

The unique focus of the model is the input of the focal, contextual and residual stimuli activity through the regulator and cognator coping mechanism to produce behavioural responses in the four interrelated adaptation models, self concepts, role function, inter dependence and physiological purposes.

Systems:

Are a set of organized components related to form a whole body, Roy considers the recipient of care to be an open adaptive system.

Input:

In Roy's system input is identified as stimuli which can come from the environment or within the person. A focal stimuli was starting IV cannulation. Input stimulates child's response to stimuli. A contextual stimuli was the weight of the baby, Type of delivery, Previous experience of IV cannulation. A residual stimuli are age, sex.

Throughput:

Throughput refers to makes use of persons processes and effectors.

Processes refers to level of pain in neonates during IV cannulation.

Effectors refers to giving oral administration of EBM to reduce IV cannulation pain.

Output:

Output is the outcome of the system. In Roy's adaptation system output is categorized as adaptive responses that promote a neonates integrity or ineffective responses. These responses provides feedback to the system. So in this study the samples who were in experimental group had a reduction in the level of pain in neonates.

Paradigms:

Human Being:

She emphasized human are individuals possesses unique potential and strives towards self direction and needy stimulation whatever the individual does ,it represents his or her best judgment at the movement .self awareness and self acceptance are essential to individuals. Sense of integrity and self worth these circumstances require respect from the nurse.

Health:

She does not define health, she supports the World health organization's definition of health.

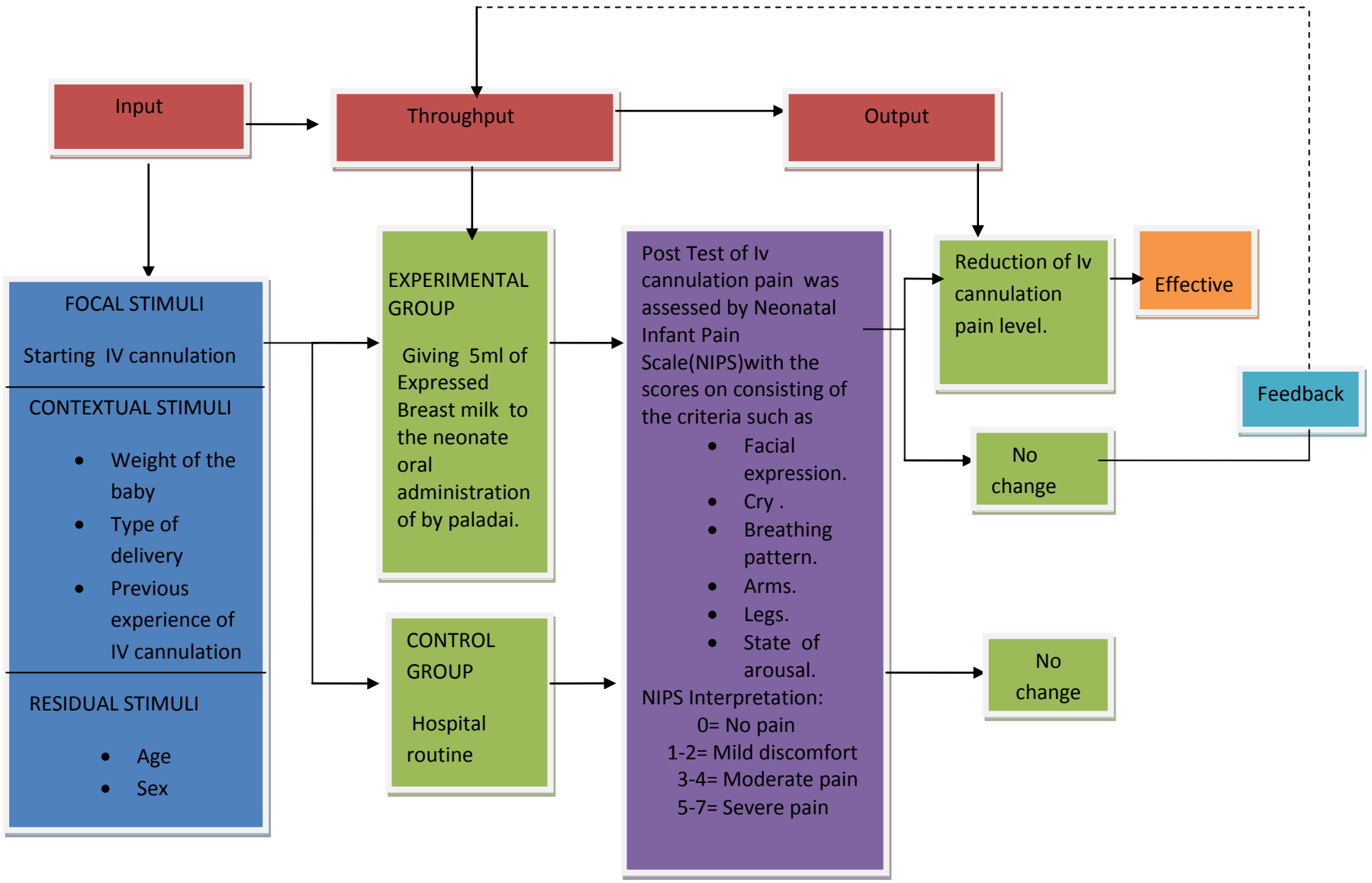
Environment:

Roy's incorporates the environment within the realities in her framework which is a complex of extraneous factors and circumstances that are present in every nursing situation .Framework includes objects such as policies , setting, atmosphere, humans and happenings.

Nursing:

Nursing is a clinical discipline, is a practice discipline designed to procedure explicit desired results. The art of nursing is goal oriented activity requiring the application of knowledge and skills towards meeting a need for help experienced by a patient .Nursing is a helping process that extends to restore the patient's ability to cope with demands implicit in the situation.

Figure 1. Callista Roy's Adaptation Model(1999)



CHAPTER -II

REVIEW OF LITERATURE

A review of literature is an eventual aspect of scientific study .It involves the systematic identification location, seeting and summary of the written materials that certain information on a research problem. It broadens the view of the investigator regarding the problem under investigation, helps in focusing on the issues especially concerning the study.

This chapter deals with the information collected in relation to the present study through published and unpublished materials which provided the foundation to carryout this study.

The literatures have been organized as follows,

- Studies related to pain assessment during minor invasive procedure among neonates.
- Studies related to non pharmacological pain reduction intervention for neonates.
- Studies related to the effect of expressed breast milk on pain reduction among neonates.

1. **Studies related to pain assessment during minor invasive procedure among neonates.**

Harrision, Denise, Loughnan, Peter(2006) conducted a postal survey on pain assessment and procedural pain management practices in neonatal units. The objective of the study was to identify current pain assessment and procedural pain management practices in neonatal units. The survey comprised questions relating to pain assessment scores, pain reduction strategies for minor painful procedures and the use of articulated policies relating to procedural pain management. Participants were the nurse unit managers or their nominees of neonatal intensive care units .The result showed that surveys were sent to 181 eligible organizations and 105 of these were returned (58%) six units (6%) used pain assessment scores on a regular basis and fifteen units (15%)had an articulated policy directing pain management practice during painful procedures non nutritive sucking and various nursing comfort measures were the pain reduction strategies most frequently used during minor painful procedures 24units (23%) used sucrose or other sweet tasting solutions during procedures. Breast feeding during venipuncture, heel launce and intramuscular subcutaneous injection was infrequently practiced and topical anesthetic agents were rarely used. They concluded that the majority of neonatal units have no articulated policy to guide pain management during painful procedures and do not regularly undertake pain assessments. Current evidence based strategies to reduce procedural pain in hospitalized infants are used infrequently.

Simon H.P Simons et.al.(2003) conducted a prospective study of procedural pain and analgesia in neonates . The objective of the study was to assess the frequency of use of analgesics in invasive procedure in neonates and the associated pain. 150 neonates were selected and recorded all painful procedures including the number of attempts required, and analgesic therapy used during the first 14 days of NICU admission. The result showed that the highest exposure to painful procedures occurred during the first day of admission, many procedures were estimated to be painful. The primitive analgesic therapy was provided to fewer than 35% of neonates per day, while 39.7% of the neonates did not receive any analgesic therapy in the NICU. The study concluded that the NICU procedures are painful, but only third of the appropriate analgesics treatment for the painful procedures is limited. Systematic approaches are required to reduce the occurance of pain and to improve the analgesic treatment of repetitive pain in neonates.

Fran Lang Porter, Cynthia M. Welf et. al (1996) conducted a survey regarding pain management in newborns. The purposes of the study was to examine the beliefs and self described behavior of physicians and nurses regarding the management of procedural pain in newborns. A survey was distributed to 467 clinicians (nurses and physicians) working in learn level II and four level III nurseries in a large metropolitan area. respondents were asked to rate the painfulness of 12 common bedside nursery procedures and low often pharmacologic and non pharmacologic measures are currently used and should be used for those procedures. The

results indicated that surveys were completed by 374 clinicians (80%response rate) physicians and nurses believe infants feel as much pain as adults and that of the 12 listed procedures are moderately very painful. Neither pharmacologic nor comfort measures are believed to be used frequently. Even for the most painful procedures. Physicians and nurses believe both pharmacologic and comfort measures should be used more frequently than do physicians. The study concluded in despite their beliefs that infants experience significant procedure related pain; clinicians believe pain management for infant's remains below optimal levels. Barriers to more consistent and effective pain management need to be identified.

II. Studies related to non-pharmacological pain reduction intervention for neonates.

Castral F, Warnock F et al. (2009) conducted a study to evaluate the effects of skin-to-skin contact during heel prick in premature infants. Fifty nine stable preterm infants (born at least 30 weeks gestational age) who were undergoing routine heel lance were randomly assigned, 31 in experimental group and 28 in control group. In experimental group the infants were kept 15min of skin-to-skin contact before, during and following heel prick, and in control group infants underwent regular care. Throughout the heel lance procedure, all infants were assessed for change in facial action (NFCS), behavioral administration of state, crying, and heart rate by using Neonatal Facial Activity Coding System (NFCS). The results showed that statistically significant differences were noted between the treatment and control groups

during the puncture, heel squeeze and the post phases of heel prick. Infants who received skin-to-skin contact were more likely to show lower NFCS scores throughout the procedure. Both groups of infants cried and showed increased heart rate during puncture and heel squeeze although changes in these measures were less for the treated infants. They concluded that Skin-to-skin contact promoted reduction in behavioral administration of measures and less physiological increase during procedure. It is recommended that skin-to-skin contact be used as a non-pharmacologic intervention to relieve acute pain in stable premature infants born 30 weeks gestational age or older.

Evelyn Cohen Reis, Erika Kraus Roth et al. (2003) conducted a study to assess the effectiveness, feasibility and parental acceptance of a simple combination pain reduction intervention for infants receiving multiple immunization injections. The infants receiving their second month immunizations, consisting of 4 injections were selected as a sample. There were 116 infants participated. Subjects were randomly assigned to the intervention or control group for administration of 4 injections. The intervention group received sucrose and oral administration of tactile stimulation and were held by their parents during immunization. The control group did not receive these interventions. The median first cry duration was 19.0 seconds for the intervention group compared with 57.5 seconds for the control group. Nurse rated ease of vaccine administration was equivalent for both treatment groups. They concluded that combining surge, oral administration of tactile stimulation, and parental holding was associated with

significantly reduced crying in infants receiving multiple immunization injections.

Larry Gray, Lisa watt and Elliott M. Blass (1999) conducted a prospective study on skin to skin contact is analgesic effect in healthy newborns. The objective of the study is to determine whether skin to skin contact between mothers and their newborns will reduce the pain experienced by the infants during heel lance. A total of 30 newborn infants were studied. The infants were assigned randomly to either being held by their mothers in whole body, skin to skin contact or to no intervention during a standard heel lance procedure. The result showed that crying and grimacing were reduced by 82% and 65%, respectively, during heel lance procedure among newborns in experimental group. Heart rate also was reduced substantially by contact. They concluded that skin to skin contact is remarkably potent intervention against the pain experienced during heel stick in newborns.

Upadhyah. A, Aggarwal. R, et al. (1998) conducted a study to assess the effectiveness of expressed breast milk (EBM) in reducing pain due to venupunture in term neonates, as measured by behavioral administration of and physiological observations. Eighty one full term neonates participated in the study. Two minutes before the venupunture 40 babies received 5 ml of EBM, while 41 babies in control group received 5 ml of distilled water. The results showed that there was no difference in the baseline characteristics of the neonates in the two groups. The duration of crying was significantly shorter (95%) in babies fed EBM than in those fed distilled water. The

modified Neonatal facial coding scores (NFCS) at 0, 1 and 3 was significantly lower in the EBM than in the distilled water group. The change in heart rate and oxygen saturation was significantly lower in the EBM group and returned to baseline values sooner than in the Distilled water group. They concluded that feeding 5 ml of EBM before venupunture is effective in reducing symptoms due to pain in term neonates.

III. Studies related to the effect of EBM on pain reduction among neonates.

Aida Abdel Razek and Nagwa AZ El-Dein (2009) conducted a study to examine the effects of breastfeeding on pain relief during neonatal immunization injections. There were 60 infants in experimental group and 60 infants in control group. In the intervention group mothers were taken to a private room, seated and reclined on a comfortable chair with their infants awake in their arms, without cloth and with clean diapers. The mothers cradled their infants during breastfeeding to maintain full body skin-to-skin contact during immunization injections. In the control group infants were observed during routine immunization. Pain responses of infants during and after immunization were assessed by using Facial Pain Rating Scale and Neonatal/Infant Pain Scale (NIPS), before, during and after the procedure. Infant's heart rates and duration of crying for both groups were calculated. Findings revealed that the crying time was shorter in intervention (breastfed) group than in the control group with a statistically significant difference in the duration of crying during and after immunization. They concluded that,

breastfeeding and skin-to-skin contact significantly reduced crying in infants receiving immunization.

Leite, Adriana Moraes et.al (2009) conducted a study to investigate the effectiveness of breastfeeding in reducing pain in newborns undergoing blood collection for newborn screening**.** The study consisted of 60 full term newborns, 31 in the experimental group and 29 in the control group. The experimental group was breastfed 5 minutes before, during, and for 5 minutes after the blood collection procedure. Neonates in the control group were held in mothers' arms but not fed or given a soother. Heart rate was considered as an index of arousal. Sucking frequency was only evaluated in the experimental group. Compared with the control group, the experimental group had significantly lower, Neonatal Facial Activity Coding System and sleep-wake state scores and heart rates changes. In the experimental group sucking frequency was highest during the first 5 minutes of breastfeeding before the procedure. The different phases of the procedure were evaluated separately; the breastfeeding intervention covered the period from 5 minutes before the blood collection until the end of recovery; sleep-wake state was fully assessed and the sucking frequency in the experimental group was assessed during the procedure. The study concluded that breastfeeding was effective in reducing pain caused by blood collection for newborn screening.

Phillips R, Chantry C, Gallagher M, (2009) Analgesic effects of breastfeeding or pacifier use with maternal holding in term infants. The objective of the study was to compare analgesic effects of breastfeeding

versus pacifier use in newborn infants undergoing blood collection via heel sticks, and to compare analgesic effects of pacifier use with maternal holding versus non maternal holding. A prospective, randomized, controlled trial design was used. There were 96 full term breastfeeding infants were selected. Infants randomized to 3 groups for analgesia breastfeeding, pacifier use while held by mothers, pacifier use while held by research assistants (non mothers). Breastfeeding infants cried than infants using a pacifier while held by non mothers both during the procedure (69% Vs 100%, P < .01) and after the procedure (28% Vs 60%, P = .03). Those infants crying during the procedure cried for less time if held by their mothers either breastfeeding (33%, P < .01) or using a pacifier (45%,P = .03) than those using a pacifier while being held by non mothers (66%).They Concluded that Breastfeeding is more analgesic than pacifier use with non maternal holding. Maternal holding with either breastfeeding or pacifier use is more analgesic than non maternal holding with pacifier use, suggesting that maternal holding itself has an analgesic effect. Breastfeeding and maternal holding should be considered as pain control measures for the neonate during heel stick procedures.

Elena Uga, Manuela Candriella (2008) conducted a study to evaluate the analgesic effect of breastfeeding during heel puncture in full term healthy newborn. They studied 200 healthy full term newborns, 100 in experimental group and 100 in control group. Pain assessment was evaluated by DAN scale (Douleur Aigue Nouveau ne scale).The findings revealed that the difference in score of pain according to the DAN scale was significant in the two groups of

patients (p = 0.000); the medium score was 5.15 for controls and 2.65 for experimental group (newborns sampled during breastfeeding).They concluded that breastfeeding is a potent analgesic intervention in newborn during heel puncture.

E. Efe, Z. Ozer (2007) conducted a study to examine the pain relieving effect of breastfeeding during immunization injections in healthy neonates. Sixty-six healthy infants returning to a clinic for their second, third, or fourth month immunization with intramuscular diphtheria, tetanus, and pertusis were randomized to be breastfed before, during, and after the injection or to be given the injection according to routine clinic procedure (no breastfeeding). To assess the pain responses of the neonates during and after immunization, they noted their heart rates, oxygen saturation levels, and length of crying. The crying time was shorter in the experimental (breastfeeding) group (M ± SD duration, 35.85 ± 40.11 seconds) than in the control group (M ± SD duration, 76.24 ± 49.61 seconds; p = .001). The heart rate and oxygen saturation levels were almost the same in both groups. They concluded that breastfeeding, maternal holding, and skin-to-skin contact significantly reduced crying in infants receiving an immunization injection or diphtheria, tetanus, and pertusis.

Modares Maryam,Vasegh Rahim Parvar S.F, et al. (2007) conducted a study to investigate the effect of breast feeding on pain control in newborns. A clinical trial design was used to evaluate analgesic effect of breast-feeding during injection of hepatitis B vaccine. 130 newborns had been

referred for hepatitis B vaccination, were selected from Mirza Kochak Khan Hospital, Tehran, Iran. After describing the procedure testimonial was took from parents. Samples were divided randomly in tow groups. In experimental group, feeding was begun two minutes before injection and continued for 45 seconds. In the control group injection was made without breast feeding. Pain assessment was performed with Douler Aigue Nouveaune (DAN) scale. The results showed that in the experimental group 35.4% of newborns got 4 points and no one got more than 7 points according to DAN scale. In contrast the control group 32.4% got 8 points or more and no one got less than 3 points. The mean of pain severity in case group was 3.5 and in control group was 6.7 and it show significant difference according to Mann-Whitney U test ($p<0.0001$).They concluded that breastfeeding can significantly reduce pain in newborns. Therefore they suggest this simple method generally for all painful procedure to prevent the development of possible permanent psychological effects in newborns.

Osinaike B.B, Oyedeji A.O. et al. (2007) conducted a study on effect of breast feeding during venupunture in neonates. There were 38 neonates participated in the study. The study was cross over design where each neonate served as his/her own control. Median pain scores during venupunture when neonates were being breastfed (BF) were compared with those when neonates were not being breastfed (NBF).The site of venupunture and numbers of previous venupunture were noted. Pain was assessed using Neonatal infant pain scale (NIPS). The results showed that the median pain score of the

neonates when breastfed was 1.5 and 4 when not breastfed. The Kruskar Wallis H-Test did not show statistically significant differences between the breastfeeding and non breastfeeding groups when the number of previous punctures and site of venupunture were considered. The study concluded that breastfeeding is analgesic in neonates during venupunture and previous venupunture and site of venupunture do not seem to affect pain scores. Breastfeeding should be the first choice analgesic during painful procedures in neonates.

Shah PS, Aliwalas L, et al. (2007) conducted a study on breastfeeding or breast milk to alternative procedural pain in neonates. The objective of the study was to compare breastfeeding with control (Placebo, no treatment, sucrose, glucose, pacifiers or positioning) and compare breast milk with control for procedural pain in neonates. Systematic review and Meta analyses of randomized and quasi randomized trial of breast feeding or supplemental breast milk for procedural pain in neonates was carried out for the studies. The results showed that the breastfeeding group has significantly less increase in the heart rate, reduced proportion of crying time and reduced duration of crying compared to the swaddled or pacifier group. Premature infant pain profile scores were lower in the breastfeeding group when compared to the placebo and the groups positioned in mother's arms, but were not different compared to the no treatment and the glucose groups. Neonates in the supplemental breast milk group had a significantly less increase in the heart rate and Neonatal Facial Coding Score but no significant difference in the

duration of crying time and oxygen saturation change compared to the placebo. They concluded that breast feeding or breast milk should be used to alleviate pain in neonates undergoing painful procedure compared to placebo, positioning, or no intervention. Administration of glucose sucrose had a similar effectiveness as breastfeeding for reducing pain.

Rayiene M. Phillips, Caroline J. Chantry, et al. (2005) conducted a study on analgesic effects of breast feeding or pacifier use with maternal holding in term infants. The objective of the study is to compare analgesic effects of breast feeding versus pacifier use in newborn infants undergoing blood collection via heel sticks. Second, to compare analgesic effects of pacifier use with maternal holding versus non maternal holding. There were 96 full term breast feeding infants scheduled for routine newborn screening blood test via hell stick (n=96)selected. The result showed that fewer breast feeding infants cried than infants using a pacifier while held by non mothers both during the procedure (69% Vs 100%) and after the procedure (28% Vs 60%). Those infants crying during the procedure cried for less time if held by their mothers either breast feeding (33%) or using a pacifier (45%) than those using a pacifier while being held by no mothers (66%). They concluded that breastfeeding is more analgesic than pacifier use with non maternal holding. Maternal holding with either breastfeeding or pacifier use is more analgesic than, non maternal holding with pacifier use, suggesting that maternal holding itself has an analgesic effect. Breast feeding and maternal holding should be

considered as pain control measures for the neonate during heel stick procedures.

Grandin.M, Finnstrom O, Schollin J (2003) conducted a study to compare the pain reducing effect of oral administration of glucose with that of being breastfed shortly before venupunture in newborns, and also the pain score and crying time with parents assessment. There were 120 full term newborns undergoing venupunture which were randomly assigned to on of four groups. Breastfed and 1 ml placebo, breastfed and 1 ml 30% glucose, fasting and 1 ml placebo, fasting and 1 ml 30% glucose. Pain during venupunture was measured with the premature infant pain profile (PIPP). The result showed that the PIPP score was significantly lower in the infants receiving glucose than in those not given glucose. There was a similar difference between newborn received breastfed and 1 ml 30% glucose and breastfed and 1 ml placebo. The median crying time during the first 3 minutes in groups I, II, III and IV were 63, 18, 142 and 93, respectively they concluded that breastfeeding shortly before venupunture has major impact on the pain score and crying time. The combination of oral administration of glucose and breastfeeding showed lowest pain score and significantly shorter duration of crying.

Gray L, Miller LW, Phillipp BL, Blass EM (2002) conducted a study to determine whether breastfeeding is analgesic in newborn infants undergoing lance a routine, painful, hospital procedure. A random sample of 30 full term breastfed infants was selected. Infants in the intervention group

were held and breastfed by their mothers during heel lance and blood collection procedures. Infants in the control group experienced the same blood test while receiving the standard hospital care of being swaddled in their bassinets. Results showed that crying and grimacing were reduced by 91% and 84% respectively, during the blood collection in experimental group. They concluded that breastfeeding is a potent analgesic intervention in newborns during a standard blood collection.

SK Jatana, SS Dalal ,CG Wilson(2003). A research was conducted to assess the analgesic effect of administration of oral administration of glucose in various concentrations, and to compare with the analgesic effects of breast milk, in neonates undergoing heel punctures during collection of blood for investigations. Neonates divided into 5 groups of 25 each. One group comprised control subjects and was administered sterile water. 3 groups were administered 1 ml of varying strengths of glucose solutions i.e. 10%, 25% and 50% respectively. The last group was given 1 ml of expressed breast milk (EBM). Other parameters like state of arousal, cry baseline heart rate (HR) and transcutaneous oxygen saturation (SpO2) were recorded. Equal strength of painful stimulus given in each procedure. The oral administration of solution was administered before 2 minutes, taking all aseptic precautions Compared to control group, all other administered solutions (10%,25%, 50% glucose and EBM) were found to reduce physiological and behavioral administration of responses in neonates undergoing heel punctures.25% and 50% glucose solutions were found to have maximal analgesic effect and both

were found to be equally effective. EBM and10% glucose solution has an equal analgesic effect but less than 25% or 50% glucose.

PS Shah,C Herbozo, LL Aliwalas (2012). A comparative study was conducted to compare the breastfeeding and breast milk with control (placebo, no treatment, sucrose, glucose, pacifiers, or positioning) for procedural pain in neonates. Marked heterogeneity in control intervention and pain assessment measures was noted. The breastfeeding group had significantly less increase in the heart rate, reduced proportion of crying time and reduced duration of crying compared to the swaddled or pacifier group. PIPP scores were lower in the breastfeeding group when compared to the placebo and the group positioned in mother's arms, but was not different compared to the no-treatment and the glucose groups. Neonates in the supplemental breast milk group had a significantly less increase in the heart rate and Neonatal Facial Coding Score but no significant difference in the duration of crying time and oxygen saturation change compared to the placebo. The inference of the study was, breastfeeding or breast milk is an effective way to alleviate pain in neonates undergoing painful procedure compared to placebo, positioning, or no intervention.

Carbajal (2003). A study was conducted to investigate whether breast feeding is effective for pain relief during venepuncture in term neonates and compare any effect with that of oral administration of glucose combined with a pacifier among 180 term newborn infants undergoing venepuncture; 45 in each group. During venepuncture infants were either breast fed (group 1), held

in their mother's arms without breast feeding (group 2), given 1 ml of sterile water as placebo (group 3), or given 1 ml of 30% glucose followed by pacifier (group 4). Video recordings of the procedure were assessed. Pain related behaviours evaluated with two acute pain rating scales: the Douleur Aigue Nouveau-ne scale and the premature infant pain profile scale. The result of the study showed that breast feeding effectively reduces response to pain during minor invasive procedure in term neonates.

PH Gray, JA Trotter, P Langbridge (2006). A cross-sectional telephone survey was carried out in hospitals regarding awareness of the benefits and the use of analgesia for minor invasive procedures in term and near term neonates in Australia. Of the total respondents, 51% and 70% respectively were aware of the benefits of sucrose and breast-feeding for neonatal analgesia. Eleven per cent of units administered sucrose before venepuncture and 25% of units used breast-feeding. Ten per cent of units used sucrose before heel prick with 49% utilizing breast-feeding. Expressed breast milk was used in 10% of units. Analgesia was given less frequently before intravenous cannulation compared to venepuncture and heel prick. There was a trend for hospitals providing a higher level of neonatal care to have a greater awareness of sucrose as an analgesic and the use of sucrose for venepuncture, heel prick and intravenous catheter insertion. Smaller units had a greater usage of breast-feeding as an analgesic for heel prick.

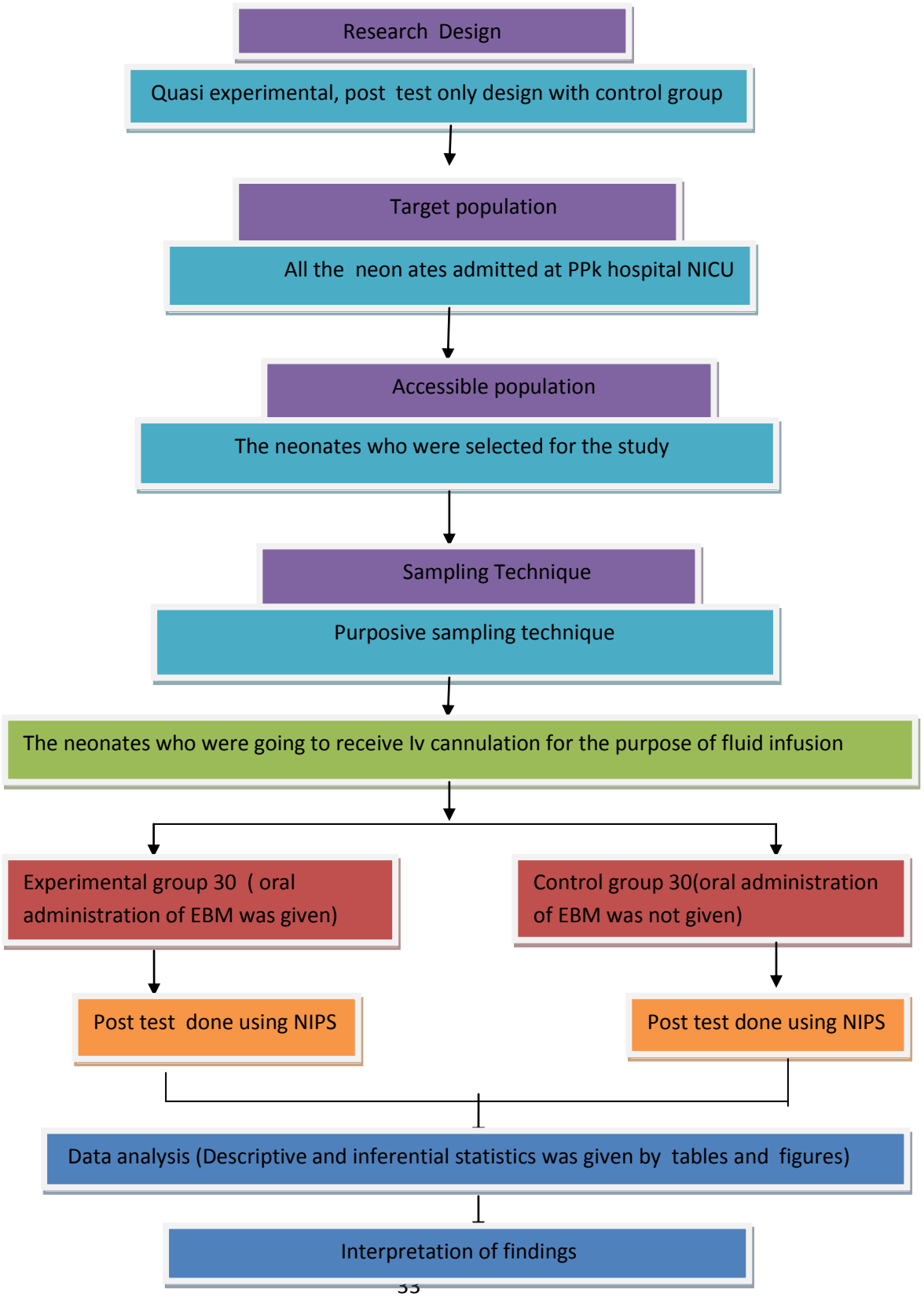
CONCLUSION:

The review of literature enlightened the investigator to develop an insight into the EBM and its effects and response of the neonates to feeding during minor invasive procedure. This review helped the investigator gained in depth knowledge of the research problem and guided her in designing the study. This review enabled the researcher to carryout the study in the effective manner.

CHAPTER - III

METHODOLOGY

Figure.2 Schematic Representation of research methodology



The information that is systematically collected in the course of a study. The chapter deals with research design, settings, population, sample, sampling technique, data collection and plan for data analysis.

RESEARCH APPROACH:

The investigator has indented to derive the pain scoring of neonates during IV cannulation in numerical values as measured by NIPS. Hence the approach was used *Quantitative research approach***.**

RESEACH DESIGN:

According to Dennise F.Polit (2011), **"**The overall plan for addressing a research question, including specification for enhancing the study's integrity" .

The research design adopted for this study is *Quasi experimental*, *Post test only design* with control group.

The design of the study is depicted below:

Experimental group (E)	X	O_2
Control group (C)	_	O_2

O_2 - Observation of pain during venipuncture in the experimental group.

O_2 - Observation of pain during venipucture in control group.

X - Intervention by administration of oral administration of EBM in the experimental group.

SETTING OF THE STUDY:

"The physical location and conditions in which data collection take place in a study". The study was conducted in PPK hospital NICU, which is 3km away from Global College of Nursing, Nattalam. The total bed strength of the hospital is 200 in that 6/day in NICU. This setting was selected because of the availability of participants and feasibility of conducting the study.

POPULATION OF THE STUDY:

It refers to, "The population that researcher wishes to include for the from study the about which the researcher wishes to make a generalization".

The target population was comprised of all neonates admitted at PPK hospital NICU.

Accessible population refers to the aggregate of cases which conform to the designated criteria and accessible to the researcher as a pool of subjects for the study.

In this study the population considered was neonates those who were in Neonatal Intensive care unit.

SAMPLE:

"Subset of the population that is selected for a study" .

The sample for a study considered of 60 selected newborns within 0 - 7days of age who required IV cannulation for fluid infusion in the selected NICU.

Group A - 30 (Experimental group: oral administration of EBM given).

Group B - 30 (Control group: oral administration of EBM was not given.

SAMPLING TECHNIQUE:

It refers to, "The process of selecting a portion of the population to represent the entire population".

The investigator has selected the sample by Purposive Sampling technique for this study, as she has intensionally selected the neonates who were going to receive IV cannulation for the purpose of fluid infusion at the selected NICU.

CRITERIA FOR SELECTION OF SAMPLING:

List of the characteristics essential for inclusion or exclusion of samples from the target population.

Inclusion Criteria:

1. Neonates who were suppose to receive IV cannulation for the purpose of fluid infusion in NICU at PPK hospital.
2. Neonates of mothers, who were willing to participate in the study.

3. Neonates between the age birth to 7 days, who had no feeding difficulty and congenital anomaly the cleft lip and cleft palate.
4. Both male and female neonates.

Exclusion Criteria:

1. Neonates those who were already on IV cannulation.
2. Neonates who did not require IV cannulation.
3. Neonates of mothers, who were not willing to participate in the study.
4. Neonates after 7 days of birth.
5. Neonates who were limb blue and unconscious and also had feeding difficulty.
6. Neonates with any congenital anomaly especially cleft lip and cleft palate.

METHOD OF DEVELOPING THE TOOL:

The tool was developed after an extensive review of literature, internet search and experts opinion. It helped the investigator to select most suitable Neonatal Infant Pain Scale (NIPS).

DISCRIPTION OF THE TOOL:

This study tool consisted of 2 sections, section A and section B.

SECTION : A

This dealt with demographic data of the neonates. It included items such as age, sex, weight of the baby, previous experience of IV cannulation.

SECTION : B

This dealt with measurement of pain experienced by the neonate with the help of NIPS (Neonatal Infant Pain Scale) developed by LAWRENCE in 1993. The Neonatal Infant Pain Scale consisted of six groups of pain related parameters for which different scoring was given.

The six parameters are mainly,

- Facial Expression
- Cry
- Breathing Difficulty
- Arms
- Legs
- State Of Arousal

At the end of pain assessment, pain level was graded based on the following scores;

0 - No pain.

1 - 2 - Mild discomfort.

3 - 4 - Moderate pain.

5 – 7 - Severe pain.

A copy of the NIPS is annexed in the appendix I.

Validity of the tool:

In this study validity of the tool was not required because the investigator has used a standardized Neonatal Infant Pain Scale developed by Lawrence in 1993 in order to assess the pain experienced by neonates.

Reliability of the tool:

Prior permission was obtained from the hospital authorities. The tool was administered to 12 neonates during IV cannulation to establish reliability .One trained personnel and investigator recorded the observation items during IV cannulation. It was checked for reliability by inter -rater reliability method by using Karl pearson quotient (r), $r = \sum dxdy / \sqrt{\sum dx^2 \times \sum dy^2}$ was found to be 0.78 which indicated that the tool was reliable. Hence it was found feasible to conduct the study.

Ethical consideration:

- The study was conducted after the approval of dissertation committee at global college of nursing.
- Formal written permission was obtained from the medical director of PPK Hospital.

- An informed verbal consent was obtained individually from parents of neonates who participated in the study.
- Confidentiality was assured to parents throughout the study.
- Parents were informed that their neonates participation were voluntary based and had the freedom to drop out from the study as when they liked to do so.

PILOT STUDY:

According to Dennise F. Polit (2011) Polit study is defined as "A small –scale version or trail run, done in preparation of a major study"

A Pilot study was conducted in Neonatal Intensive Care Unit(NICU) of PPK hospital from 10-2-2014 to 15-2-2014 after obtaining formal administrative and ethical approval and consent from parents of neonates. By using purposive sampling technique 12 neonates were selected as sample. Out of 12 ,6 samples were allotted to the experimental group and 6 were allotted to the control group . Pain was assessed during the IV cannulation . In experimental group pain was assessed with oral administration of EBM to the procedure. In control group the pain was assessed without any intervention. The pain score was assessed with NIPS (Neonatal Infant Pain Scale). The pilot study did not show any major problems and the timing and intervention plan were found to be feasible.

DATA COLLECTION PROCEDURE:

After having obtained a formal written permission from to administrative officer of PPK hospital, the final study was conducted from 17-2-2014 to 17-3-2014 on 60 neonates from NICU of PPK hospital. Neonates were identified as per the inclusion criteria .Subjects were selected using purposive sampling method and assigned to the experimental and control groups. The investigator select the neonates receiving IV cannulation in NICU.

The details of the study was explained to parents and a verbal consent was obtained. The information are collected as per the demographic proforma. The pain was assessed by NIPS during IV cannulation if it was only for fluid infusion. In experimental group oral administration of EBM was given before the procedure and pain assessment was done .In the control group observation of pain was made for 30 neonates where no intervention was given.

PLAN FOR DATA ANALYSIS:

Descriptive and inferential statistics were used to analyze the data. Analysis of demographic variables was done in terms of frequency and percentage distribution of the post test level of pain in the experimental and control group. Comparison of post test level of pain between the experimental and control group was done using central tendency such as mean, standard deviation and t-test techniques. Association of post test level of pain in the control group with their demographic variables was done by using chi-square test.

CHAPTER- IV

DATA ANALYSIS AND INTERPRETATION

In this study the purpose of analysis was to reduce the collected data in an intelligible and interpretable form using different statistical methods such as descriptive and inferential statistical analysis.

According to Polit and Hungler (2005) analysis is the method of organizing, sorting and scrutinizing data in such a way that research question can be answered.

This chapter deals with the analysis and interpretation of data collected from 60 neonates (30 Experimental and 30 control group) on reducing pain to evaluate the effect of oral administration of EBM given just before starting IV cannulation in reducing cannulation pain among neonates in the selected hospital at Kanyakumari District.

The analysis and interpretation of data were based on data collection and the results were computed by using descriptive (mean ,frequency ,percentage distribution and standard deviation) and inferential ('t'-test and chi-square test) statistics and the results were interpreted in tables, fingers and diagrams.

Statistical analysis used:

The findings of the study were grouped and analyzed under the following sections.

Section A: The frequency percentage distribution of the Post test level of pain in the experimental and control groups was an descriptive statistics.

Section B: The frequency percentage distribution of post test level of pain in the experimental and control group.

Section C: The comparison of post test level of pain between the experimental and control groups was analysed by ‘t’test. Which is an inferential statistical analysis.

Section D: The Association of post test level of pain in the control group with demographic variables was analysed by using ‘chi-square’test.

SECTION :A

Table-1 Frequency Percentage distribution of demographic variables in the experimental group and control group

DEMOGRAPHIC VARIABLES	EXPERIMENTAL GROUP		CONTROL GROUP	
	NO	%	NO	%
Age in days				
Birth -2days	24	80	25	83.33
3-5 days	5	16.67	3	10
6-7days	1	3.33	2	6.67
>7days	0	0	0	0
Sex				
Male	14	46.67	12	40
Female	16	53.33	18	60
Weight of the baby				
<2.00kg	0	0	0	0
2.01-2.250kg	0	0	0	0
2.251-2.500kg	4	13.33	21	70
2.501-3.000kg	24	80	5	16.67
>3.000kg	2	6.67	4	13.33
Type of delivery				
Normal	9	30	10	33.33
LSCS	21	70	20	66.67
Forceps	0	0	0	0
Vacuum	0	0	0	0
Previous experience of IV cannulation				
Yes	3	10	1	3.33
No	27	90	29	96.67

The above table depicts that regarding Age - among 30 neonates in the experimental group majority of 80% were aged between birth -2days and among 30 neonates in the control group 83.33% were between 0-2 days with regard to age .

Sex: among 30 neonates 53.33% females were in the experimental group and among 30 neonates 60% were females in the control group.

Weight of the baby: among 30 neonates 80% in weight of the baby between 2.501-3.000kg in experimental group and among 30 neonates 70% in weight of the baby between 2.251 – 2.500kg in the control group,

Type of delivery: among 30 neonates 70% babies are LSCS delivery in the experimental group and among 30 neonates 66.67% babies are LSCS delivery in the control group.

Previous experience of IV cannulation: among 30 neonates 90% were no previous experience of IV cannulation and whereas in the control group among 30 neonates 96.67% were no previous experience of IV cannulation.

FIGURE-3.1 Frequency Percentage distribution of age in days in the experimental and control Groups

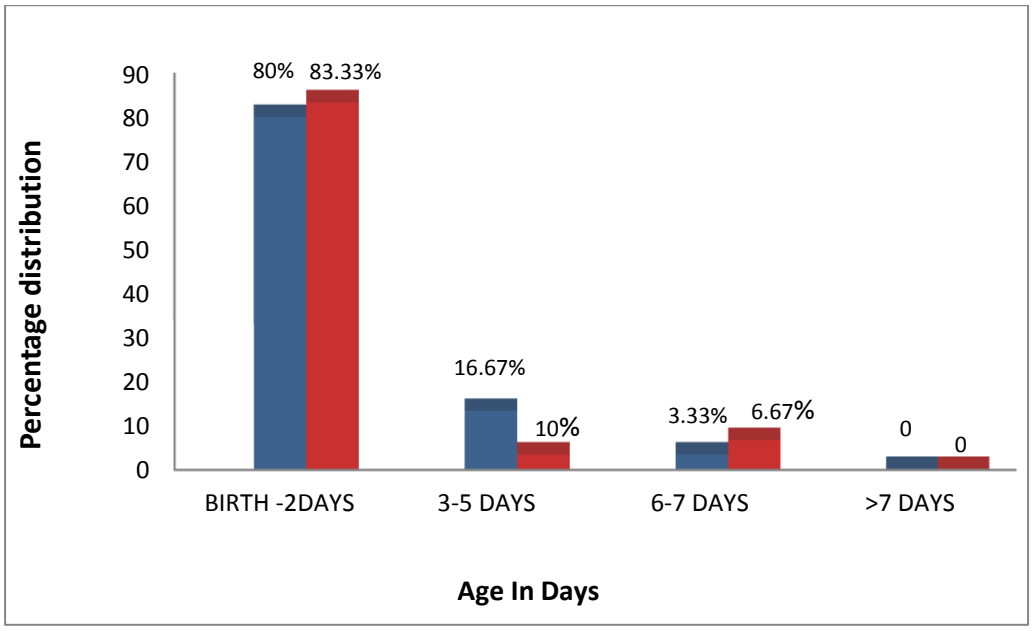


FIGURE-3.2 Frequency Percentage distribution of sex in the experimental and control groups

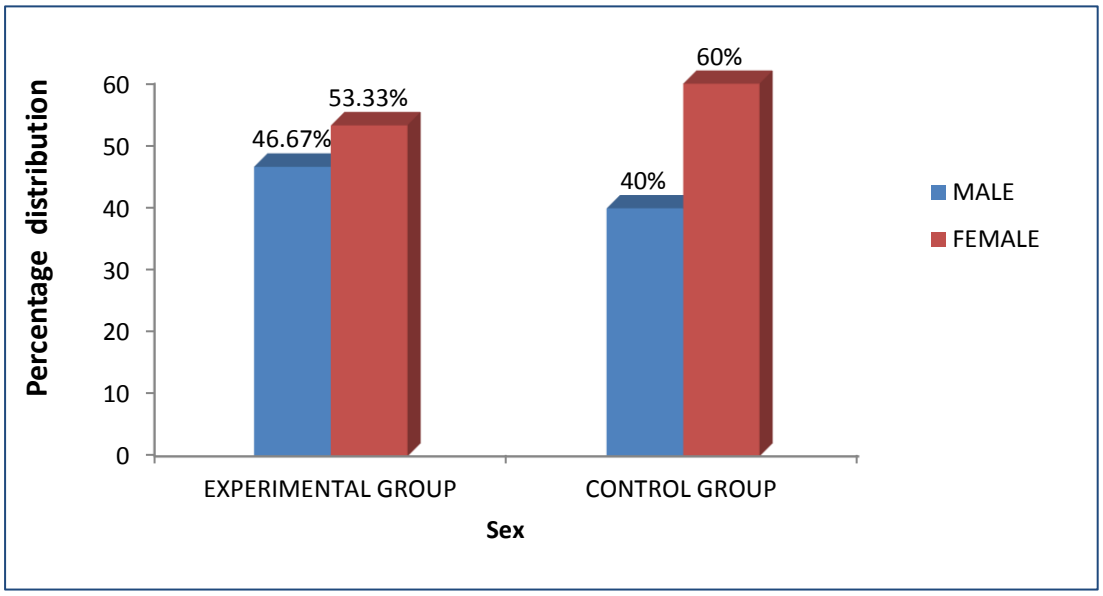


FIGURE -3.3 Frequency Percentage distribution of weight of the baby in the experimental and control groups

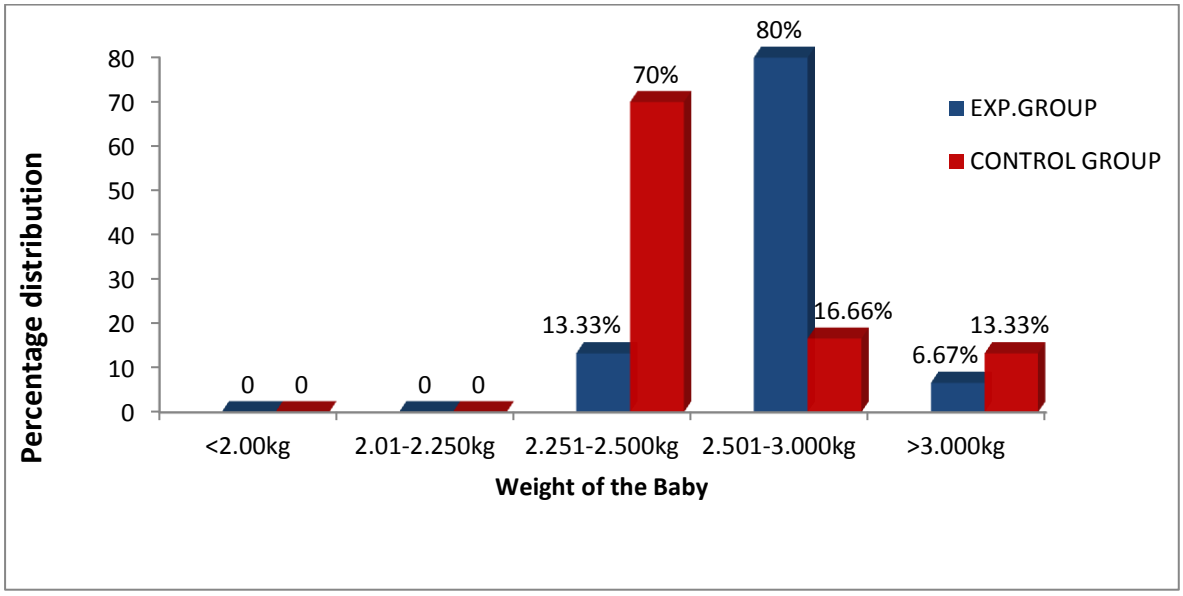


FIGURE-3.4 Frequency Percentage distribution of type of delivery in the experimental and control groups

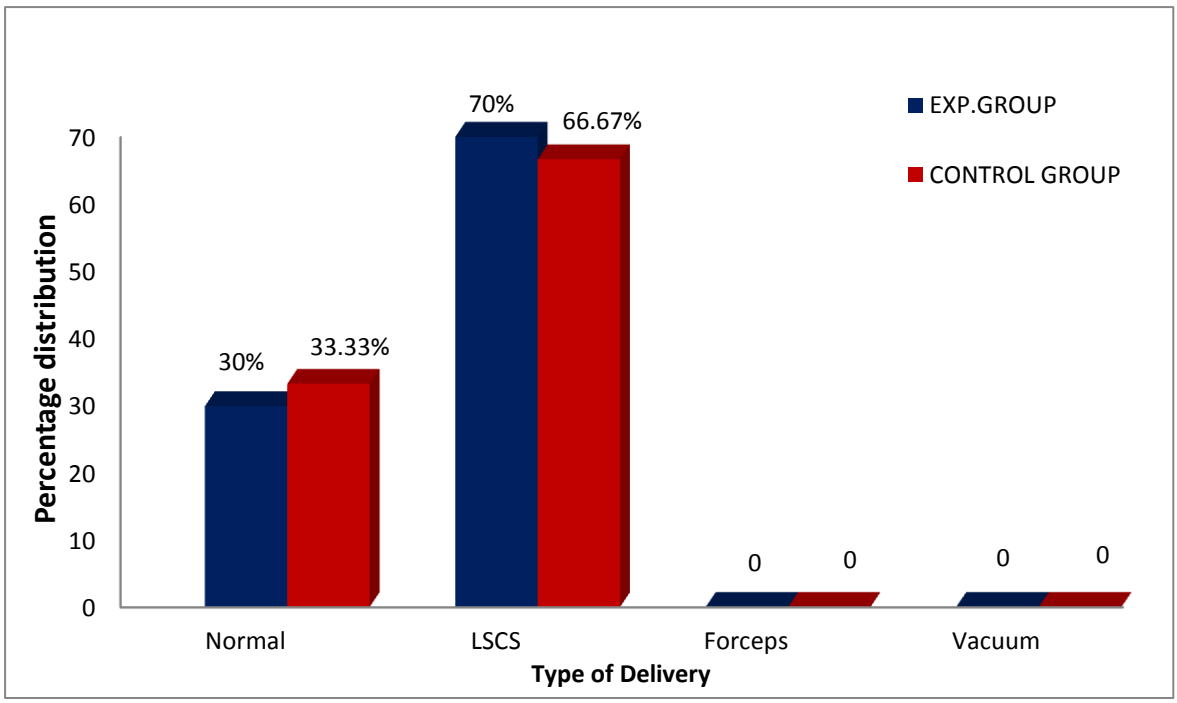
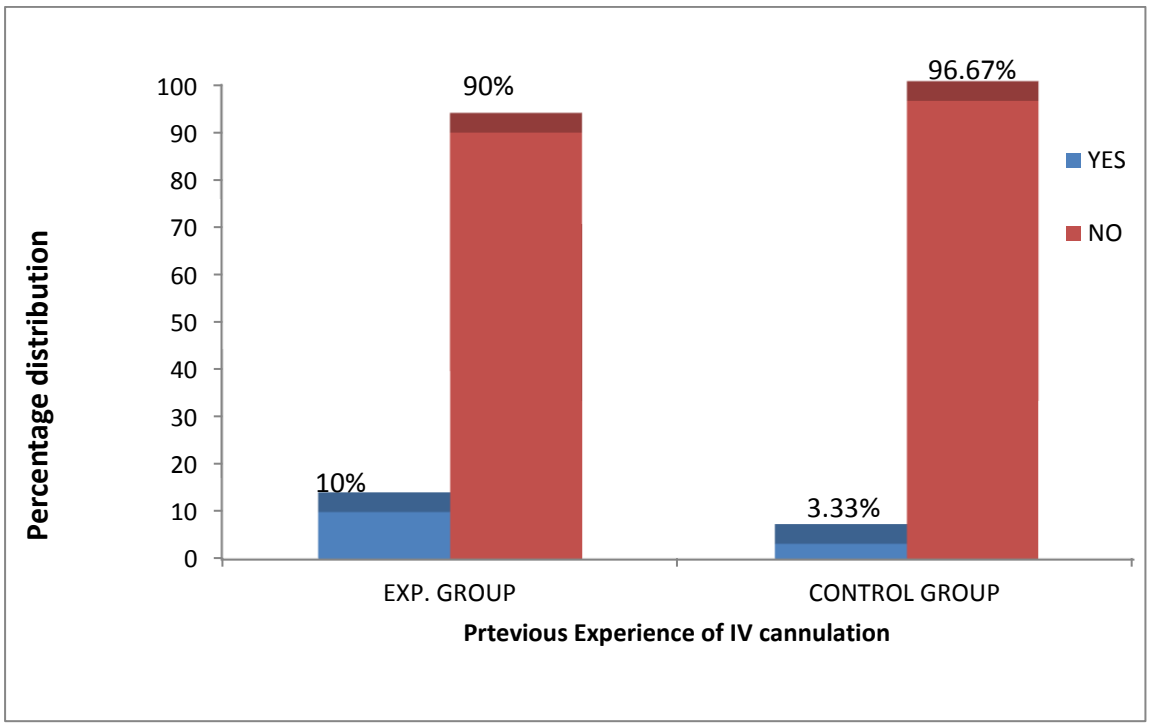


FIGURE.3.5 Frequency Percentage distribution of previous experience of IV cannulation in the experimental and control group



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SECTION :B

TABLE: 2 Frequency percentage distribution of post test level of pain in the experimental group and control group

Group	No Pain		Mild Pain		Moderate Pain		Severe Pain	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Experimental Group	0	0	16	53.33	14	46.66	0	0
Control Group	0	0	0	0	14	46.66	16	53.33

The Table :3 shows that in the experimental group majority 16 (53.33%) had mild pain, 14 (46.66%) had moderate pain and in control group majority 16(53.33%)had severe pain**,** 14 (46.66%) had moderate pain.

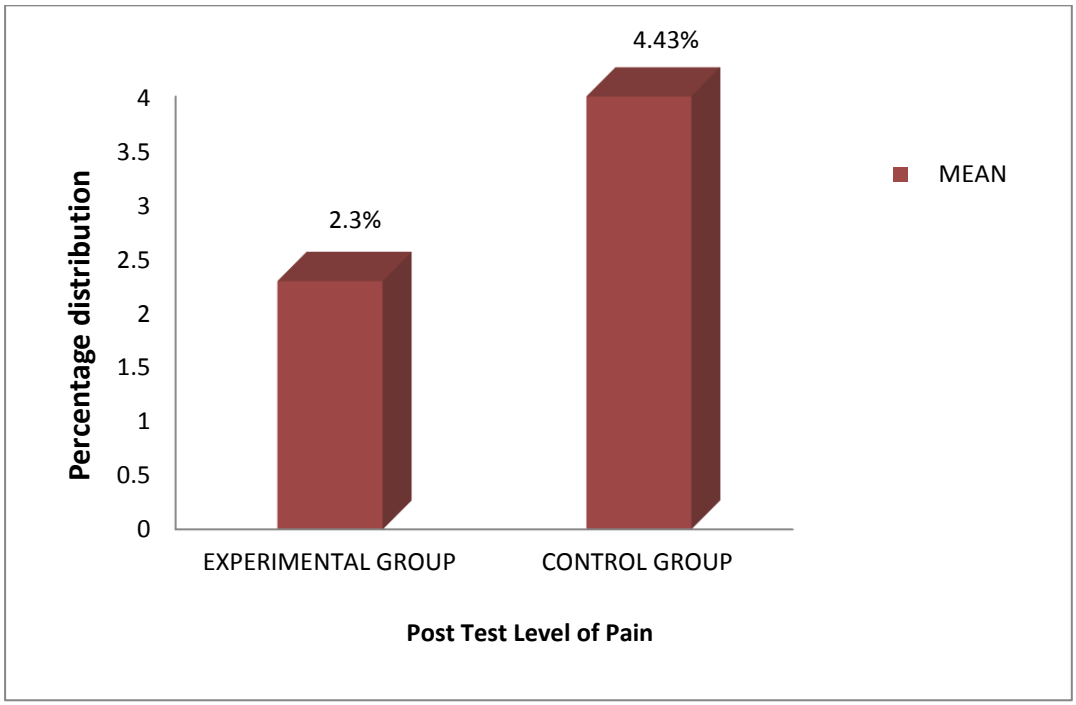
SECTION :C

Table:3 Comparison of post test level of pain between the experimental and control group

POST TEST Level of pain	Mean score	S.D	Mean difference	t value
Experimental group	2.3	0.822	2.13	8.247* (s)
Control group	4.43	1.054		

Table:3 depicts that in the experimental group, the post test level of mean pain score was 2.3 with S.D 0.822 and in the control group the post test mean score was 4.43 with S.D 1.054. The mean difference score was ± 2.13. The calculated 't' value of 8.247 was statistically significant at $P<0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

FIGURE-3.6 Comparison of post test level of pain between the experimental and control groups



SECTION- D

Table:4 Association of post test level of pain in the control group , with the subjects demographic variables

n=30

Demographic variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-square Value
	No	%	No	%	No	%	No	%	
Age in days									2.26 df=2 (NS)
Birth-2days	0	0.00	0	0.00	12	40	13	43.33	
3-5days	0	0.00	0	0.00	2	6.67	1	3.33	
6-7days	0	0.00	0	0.00	0	0.00	2	6.67	
>7days	0	0.00	0	0.00	0	0.00	0	0.00	
Sex									0.088 df= 1 (NS)
Male	0	0.00	0	0.00	6	20	6	20	
female	0	0.00	0	0.00	8	26.67	10	33.33	
Weight of the baby									0.494 df= 2 (NS)
<2.00kg	0	0.00	0	0.00	0	0.00	0	0.00	
2.01-2.250kg	0	0.00	0	0.00	0	0.00	0	0.00	
2.251-2.500kg	0	0.00	0	0.00	3	10	2	6.67	
2.501-3.000kg	0	0.00	0	0.00	9	30	12	40	
>3.000kg	0	0.00	0	0.00	2	6.66	2	6.67	
Type of delivery									0.265 df= 1 (NS)
Normal	0	0.00	0	0.00	4	13.33	6	20	
LSCS	0	0.00	0	0.00	10	33.33	10	33.34	
Forceps	0	0.00	0	0.00	0	0.00	0	0.00	
Vacuum	0	0.00	0	0.00	0	0.00	0	0.00	
Previous experience of IV cannulation									0.904 df=1 (NS)
Yes	0	0.00	0	0.00	0	0.00	1	3.33	
No	0	0.00	0	0.00	14	46.67	15	50	

NS-Not significant

Table:4 shows that the demographic variables had not shown any statistically significant association with the level of pain in the control group. This could be due to smaller sample size.

CHAPTER- V

DISCUSSION

The main aim of the study was to assess the effect of oral administration of EBM just before starting IV cannula in reducing cannulation pain among neonates in the NICU. The study was conducted by using quasi experimental design with post test only design with control group. The present study was conducted in PPK hospital, Marthandam, Kanyakumari District. The sampling technique is purposive sampling technique was used for this study . The total sample size was 60, among them 30 were in the group A and 30 were in the group B. Neonatal Infant Pain Scale (NIPS) developed by Lawerence 1993 was used for data collection. After data collection, data was organized, tabulated, summarized and analyzed. The study findings were discussed in this chapter with reference to the objectives of the study.

The objectives were,

- To assess the level of pain during IV cannulation after oral administration of EBM in the group A and without EBM in group B.

- To assess the effect of EBM in reducing cannulation pain by comparing the Pain level between group A and group B.

- To determine the association between the level of pain in group B during IV Cannulation and their demographic variables such as age,sex, weight of the baby,type of delivery ,previous experience of IV cannulation.

The frequency and percentage distribution of demographic variables in the experimental group majority 24(80%) were age between birth -2 days,16(53.33%) in female, 24(80%) weight of the baby 2.501 -3.000kg, 21 (70%) babies are LSCS delivery, 27(90%) were no previous IV cannulation,

whereas in the control group, majority 25 (83.33%) were age between birth-2 days, 18(60%) in female, 21(70%) in the weight of the baby 2.251 – 2.500kg , 20 (66.67%) babies are LSCS delivery , 29(96.67%) were no previous experience of IV cannulation.

The first objective was to assess the level of pain during IV cannulation after oral administration of EBM in the group A and without EBM in group B.

In the experimental group majority 16(53.3%) had mild pain and control group majority 16 (53.3%) had severe pain.

The study findings were consistent with the study conducted by oral administration of dextrose on pain level of neonates under venipuncture also showed experimrental group 46.67% had mild pain and control group 53.33% had severe pain.

The second objective was to assess the effect of EBM in reducing cannulation pain by comparing the pain level between group A and group B.

In the experimental group , the post test level of mean pain score was 2.3 with S.D 0.822 and in the control group the post test mean score was 4.43 with S.D 1.054. The calculated 't' value of 8.247 was statistically significant at $p<0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

Hence the null hypothesis Ho stated that there is no significant difference of pain level during IV cannulation between group A and group B.

The study findings were consistent with the study conducted by Osinaike (2007) the effect of breast feeding during venipuncture in neonates .The SD score (interquartile range) of the neonates when breastfed was 1.50(1-2) and 4.00(2-6) when not breast feed ($p=0.0001$).

The third object was to determine the association between the level of pain in group B during Iv cannula and their selected demographic variables

The association table that the demographic variables had not shown any statistically significant association with the level of pain in the control group.

The conceptual framework of this study was based on Callista Roy's adaptation model (1999). This model describes the goal of nursing is to facilitate adaptation between person and the environment through the management of stimuli. The focal stimuli is considered as IV cannula insertion because the neonates pain is related responses were tested as a result of intravenous therapy. The contextual stimulus such as weight of the baby, type of delivery, previous experience of IV cannulation and residual stimuli are age and sex as a response to focal, contextual and residual stimuli the responses exhibited out in physical and psychological aspects. The physical responses to pain are facial expression, crying, breathing pattern, arms restrained, leg restrained, state of arousal and psychological response. The investigator given oral administration of EBM to neonates and assess the pain level through (NIPS) by evaluation of post assessment level of pain.

The findings concluded that the neonate in the experimental group had reduction in the level of pain when compared with control group .Hence the EBM was responsed to reduce the IV cannulation pain among neonates.

CHAPTER VI

SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter deals with summary, conclusion, limitations and recommendations for further studies. Further it includes implications of findings of this study in Nursing Practice, Nursing Education, Nursing Administration and Nursing Research.

SUMMARY OF THE STUDY

The aim of the study was to assess the effect of oral administration of expressed breast milk just before IV cannulation in reducing cannulation pain among neonates in NICU in PPK hospital, Marthandam ,Kanyakumari District.

The objectives of the study were,

- To assess the level of pain during IV cannulation after oral administration of EBM in group A and without oral administration of EBM in group B.
- To assess the effect of EBM in reducing cannulation pain by comparing the pain level between groups A and group B .
- To determine the association between the level of pain in group B during IV cannulation and their demographic variables such as age,

sex , weight of the baby, type of delivery, H/o previous experience of IV cannulation,if yes specify when.

The target population is comprised of all neonates admitted at ppk hospital NICU.

Accessible population refers to the aggregate of cases which conform to the designated criteria and which to accessible the researchers as a pool of subjects for the study. In this study is comprised of neonates those who are in Neonatal Intensive care unit. The physical location and conditions in which data collection take place in a study. The study will be conducted in PPK hospital NICU. It is 3km away from Global College Of Nursing, Nattalam. The total bed strength of the hospital is 200. This setting was selected because of the availability of participants and feasibility of conducting the study.

A quasi experimental design in nature .Post test only design with control group was chosen for this study. Purposive sampling technique was used for this study. Subjects were selected based upon the inclusion and exclusion criteria. 60 subjects were selected for the study. Purposively 30 Subjects were assigned to group A and 30 subjects were assigned to group B.

The tool used to collect the data consisted of two parts, section A: consisted of the demographic Variables with age, sex, weight of the baby, type of delivery, H/o previous experience of IV cannulation. Section B

consisted of NIPS (Neonatal Infant Pain Scale) developed by Lawrence in 1993. NIPS interpretation:

0	-	No pain.
1 - 2	-	Mild discomfort.
3 - 4	-	Moderate pain.
5 – 7	-	Severe pain

validity of the tool was not obtained because the investigator selected a standardized Neonatal Infant Pain Scale developed by Lawrence in 1993. Reliability of the tool was tested by using test-retest method the formula was, $r=\sum dxdy/\sqrt{\sum dx^2 \times \sum dy^2}$ $(r = 0.78)$. Data collection was done for 4 weeks. Sample subjects were selected based on the inclusion and exclusion criteria. Demographic variables were collected. Post test was done by using Neonatal Infant Pain Scale. Intervention was done with oral administration of administration of 5ml of expressed breast milk to the selected neonates by using paladai just before introducing a sterile cannula into vein of the neonates .

After that collected data were analyzed by both descriptive statistics (inclusive of mean, standard deviation , frequency and percentage) and inferential statistics (inclusive of dependent and paired ‘t’ test ,chi-square) and results were interpreted in the forms of tables ,figures and diagrams.

Major Findings of the Study:

With regard to the level of cannulation pain among neonates, most of them were found to have severe and moderate pain in the group B, as measured by NIPS and group A exhibited only moderate and mild . It revealed that the pain during cannulation which denotes that the reduction of pain was due to administration of oral administration of EBM.

Age: among 30 neonates in the experimental group majority of 80% were aged between birth -2days and among 30 neonates in the control group 83.33% were between 0-2 days .

Sex: among 30 neonates 53.33% females were in the experimental group and among 30 neonates 60% were females in the control group.

Weight of the baby: among 30 neonates 80% in weight of the baby between 2.501-3.000kg in experimental group and among 30 neonates 70% in weight of the baby between 2.251 – 2.500kg in the control group,

Type of delivery: among 30 neonates 70% babies are LSCS delivery in the experimental group and among 30 neonates 66.67% babies are LSCS delivery in the control group.

Previous experience of IV cannulation: among 30 neonates 90% were no previous experience of IV cannulation and whereas in the control group among 30 neonates 96.67% were no previous experience of IV cannulation.

The pain mean score of group A was 2.3 with standard deviation 0.822 and group B mean score was 4.43 with standard deviation 1.054. The mean difference was 2.13. The obtained‘t’ value was 8.247, where as the table value was 3.46. It was significant at $p< 0.001$ level.

It was inferred that oral administration of EBM was highly effective in reducing IV cannulation pain among neonates receiving IV cannula.

With regard to the association between the level of IV cannulation pain and selected demographic variables in group B. The study findings had revealed that in post test in the group B there was a no significant association with the level of pain.

CONCLUSION:

The study finally concluded that administration of 5ml expressed milk just before starting IV cannulation for neonates on Iv infusion ,has a positive effect on reducing pain for the neonates. This conclusion was made based on the ‘t’test value which was found to be highly significant.

IMPLICATIONS OF THE STUDY FINDINGS:

Nursing implications denotes the utility of study findings in various fields of nursing such as Nursing practice, Nursing education, Nursing administration and Nursing research.

Nursing Practice :

- Oral administration of EBM for IV cannulation pain management can be included as nursing procedure to while providing care for neonates during IV cannulation.
- The mothers of neonates undergoing IV cannulation can be encouraged to carry out this method if nurses are occupied by IV cannulation procedure.
- EBM alleviates the anxiety and discomfort with in the mother who may feel very much comfortable and happy due to pain reduction in the baby and the baby is calm.
- The oral administration of administration of EBM can be effectively instituted in the NICU as the neonates are temporarily separated from mother.

Nursing Education:

- Administration of oral administration of EBM during IV cannulation for neonates can be included in the curriculum for 3rd year Bsc nursing course ,along with neonatal care in the NICU.
- Nursing students should be supervised by instructors while administering oral administration of EBM during IV cannulation so that it can become a routine in NICU.

- Adequate inservice training can be given to the nursing staff and students regarding oral administration of EBM in reducing IV cannulation pain.
- Health education can be given to mothers of newborns in NICU.

Nursing Administration:

- The Nurse administrators can initiate oral administration of EBM to reduce the IV cannulation pain through developmental programme like in-service education and continuing nursing education programme.
- Nurse administrator can prepare written policies and protocols regarding administration of oral administration of EBM during IV cannulation for all neonates in NICU.

Nursing Research:

- The nurse researcher can conduct many more studies in different areas of neonatal units to bring about newer perspective in nursing care.
- The study finding will motivate the initial researchers to conduct the same study on large scale and study will be the reference for the extensive and intensive nursing care.

Limitation:

No limitation was encountered by the investigator during or after the study.

Recommendations:

- A similar study can be replicated on a large sample size.
- A similar study can be conducted in different settings such as newborn care units or infant care units.
- A similar study can be done with other intervention to reduce IV cannulation pain such as direct breast feeding to neonates during IV cannulation or various non pharmacological interventions.

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APPENDIX-I

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GLOBAL COLLEGE OF NURSING

Recognised by the TNC & INC
Affliated to Tamil Nadu Dr. M.G.R. Medical University
Edaivilagam, Nattalam, Kanyakumari District.

Off: S.G. Multi Speciality Hospital, Old Theatre Jn, Pammam, Marthandam - 629 165,
K.K. Dist., Tamil Nadu. Mob : 9443606955, 9944110448.

17/02/2014

To

The Administrator,
P.P.K. Hospital,
Marthandam.

Sir,

Sub: Requisition for the grant of consent to conduct a Research at your promise-Reg.

As **Ms. Janeefa shiny** II year M.Sc. (N) student of Global College of Nursing, Nattalam, requires to conduct a research towards completion of their programme, I request you to kindly grant her permission to conduct the study stated below:

A STUDY TO ASSESS THE EFFECT OF ORAL EBM JUST BEFORE STARTING IV CANNULA IN REDUCING CANNULATION PAIN AMONG THE NEONATES AT SELECTED HOSPITAL IN KANYAKUMARI DISTRICT.

Thanking You,

Yours faithfully

(PRINCIPAL)
GLOBAL COLLEGE OF NURSING
EDAVILAGAM,
NATTALAM, MARTHANDAM

Principal
GLOBAL COLLEGE OF NURSING
Edavilagam, Nattalam,
Kanyakumari District - 629 165

GLOBAL COLLEGE OF NURSING ★ NATTALAM, K.K.I

Permitted.

A. MATHIVANAN MBA
ADMINISTRATIVE OFFICER
PPK HOSPITAL
MARTHANDAM - 629 [illegible]

P.P.K. HOSPITAL ★ PIN: 629 165 ★ MARTHANDAM

APPENDIX-II

Tools For Data Collection

Section : A

Demographic variables

1. Age in days
   a) Birth-7 days
   b) 8-14 days
   c) 15-21 days
   d) 22-28 days ( )

2. Sex
   a) Male
   b) Female ( )

3. Weight of the Baby
   a) <2.00 kg
   b) 2.01-2.250 kg
   c) 2.251-2.500kg
   d) 2.501 – 3.000kg ( )
   e) > 3.000kg

4. Type of delivery
   a) Normal
   b) LSCS
   c) Forceps ( )
   d) Vacuum

5. Previous experience of IV cannulation
   a) Yes
   b) No
   ( )

Section : B

Neonatal Infant Pain Scale (NIPS) Lawrence. J Alcock D et al. the development of a tool to assess neonatal pain. Neonatal network 1993. 12(6 September) 59-66.

1. Facial expression
2. cry
3. Breathing Patterns
4. Arms
5. Legs
6. State of arousal

Sl.No.	Parameter	Findings	Points
1	Facial expression	Relaxed	0
		Grimace	1
2	Cry	No cry	0
		Whimper	1
		Vigorous cry	2
3	Breathing patterns	Relaxed	0
		Change in breathing	1
4	Arms	Restrained	0
		Relaxed	0
		Flexed	1
		Extended	1
5	Legs	Restrained	0
		Relaxed	0
		Flexed	1
		Extended	1
6	State of arousal	Sleeping	0
		Awake	0
		Fussy	1

Minimum Score : 0
Maximum Score :7 ; NIPS Interpretation: 0 =No pain; 1to 2 = Mild discomfort; 3 to 4=Moderate pain; 5 to 7=Severe pain.

SECTION-C

In experimental group 5ml of breast milk released manually from the mother's breast by fixing a pump and giving to the selected neonates orally by paladai just before introducing a sterile cannula into vein of the neonates and pain assessment was done with in a minutes. In the control group observation of pain was made for 30neonats where no intervention was given.